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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,067	10/09/2003	Mark B. Knudson	11587.1USCA	9479

22852 7590 04/11/2006

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EXAMINER
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ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/682,067

Applicant(s)

KNUDSON ET AL.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-25 and 31-64 is/are pending in the application.
- 4a) Of the above claim(s) 17, 23 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 18-22, 24 and 31-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/26/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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***Election/Restrictions***

Applicant's election without traverse of the implant as embodied in figure 3A in the reply filed on 1/10/2006 is acknowledged.

Claims 17,23,25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/10/2006.

Claims 1-15 and 26-30 have been cancelled. Currently claims 16,18-22,24 and 31-64 are pending for action.

***Claim Rejections - 35 USC § 102***

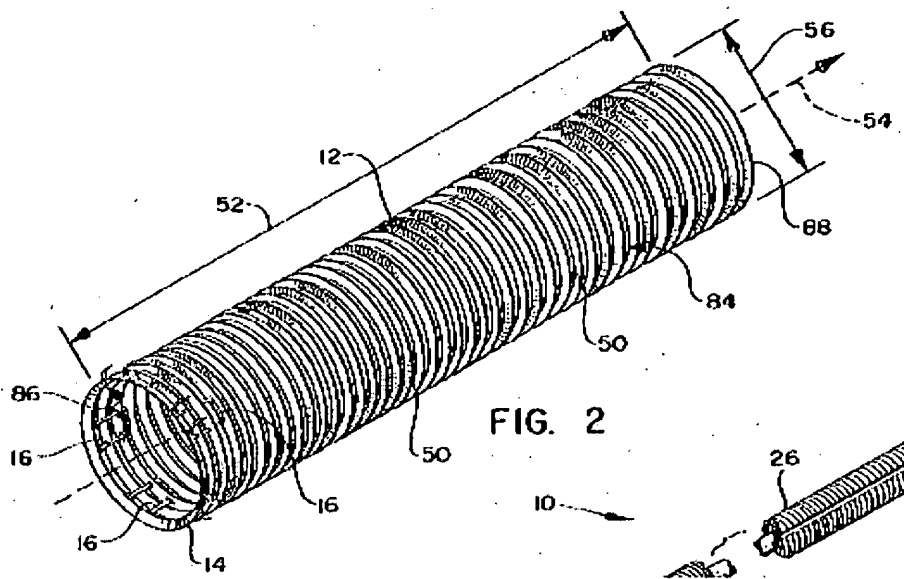
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16,18-21,24,31,32,34,36,38,39,51,52,54,56,57,58,59,60,61,62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus [4787899].

Lazarus discloses a conduit comprising a hollow conduit having an interior and an exterior wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place.



The language “for use in a wall of a heart” and “adapted to positioned in the heart wall between a coronary vessel and a chamber in the heart” is directed to a method for using the “bypass conduit” and does not, in itself serve to further limit the structure of the conduit. Lazarus discloses a conduit that is for use in a lumen (eg. blood vessel or artery). The properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart.

Claim 18 is directed to a method step of locating the left ventricle as the chamber. The claim does not further limit the structure or function of the device.

Claim 19, see barbs as illustrated in figures 3 and 4 of Lazarus.

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Claims 20 and 21, the function of the barbs, as disclosed by Lazarus, perform the function of anchoring the conduit to a soft tissue. The claims are directed to a method step for locating the anchor to a particular tissue and does not serve as further limiting the structure of the device as claimed.

Claim 24, the claim is similar to claim 16 and is broadly readable on Lazarus. The recitation of "a vessel supporting mechanism does not distinguish over the barbs of Lazarus.

Claim 31, see rejection to claim 21 supra.

Claim 32, the conduit of Lazarus is designed to remain open during both systole and diastole and therefor meets the functional limitation of the claim.

Claim 34, see lumen 12.

Claim 36, the conduit of Lazarus is designed to remain open during both systole and diastole and therefor meets the functional limitation of the claim.

Claim 38, the conduit of Lazarus is deformable so as to conform to the interior surface of the tissue in which it is placed.

Claim 39, the barbs are configured for attaching to the inner surface of the tissue.

Claims 51,52,54,56,57,58,59,60,61,62 and 64, see rejections supra corresponding to the particular claimed subject matter in each claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18-21, 22, 24, 31-36, 38-45, 47-62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899] in view of either of Robinson [4604762] or Lee [5123917].

While the device of Lazarus does not have additional supporting structures to aid in biasing the conduit to a non-collapsed position, each of Robinson and Lee teach the addition of flexible rings along the length of the conduit to provide strength to the conduit to resist collapsing of the lumen. To add supporting rings along the conduit of Lazarus to provide additional strength for biasing the lumen into an open position would have been obvious to one with ordinary skill in the art from the teachings of either of Lee or Robinson.

Claims 18-21, 31-36, 38-45, 47-62 and 64, see rejections supra (see 102 rejections under Lazarus) corresponding to the particular claimed subject matter in each claim.

Claims 37, 46 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus [4787899] as modified and as applied to the claims above, and further in view of Bowen [2127903].


Bowen shows various known configuration of conduits used for augmentation and/or reconstruction of various in vivo tissues, organs and vessels. To form the conduit of Lazarus in a non-linear conduit as illustrated in figures 6, 7 and 7a to better meet the in vivo applications and tissue requirements would have been obvious to one with ordinary skill in the art based upon routine surgical considerations.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
4/3/2006